Abstract 295

TITLE: Microbicide Product Development: Research Overview
AUTHOR: Harrison, Polly, Alliance for Microbicide Development

ISSUE: At the 1994 International Conference on Population and Development in Cairo, the need for topical vaginal microbicides was assigned high priority. When a first-ever formal tally was taken that same year, 22 microbicidal products were in development but over half were still in the preclinical stage and none had reached Phase Ill for safety and efficacy testing in human subjects prior to FDA market approval.
SETTING: Public-and private-sector basic and applied research entities.
PROJECT: The Alliance for Microbicide Development, a consortium of companies, scientists, and advocates working toward development of topical microbicides, compiled a database of all published and unpublished research to date on topical microbicide products. This database has been reviewed by both public and private sector investigators, and is constantly revised and updated to keep track of emerging product developments.
RESULTS: Progress since 1994 would seem to be substantial. Overall, around 50 vaginal microbicides are being worked on by small biopharmaceutical companies, academically-based research groups, and nonprofit organizations. Approximately 30 products have spermicidal and anti-microbial activity, 16 are anti-microbial only, 6 are spermicides with possible anti-microbial activity, and 4 have spermicidal effect only. Roughly half act by killing or mucosal cells, 6 inhibit cell fusion, and a half-dozen work primary by inhibiting post-fusion event. Yet, despite the considerable increase in the number of microbicidal products in the R&D pipeline, only 3 have reached Phase III, just 4 are in Phase 11, 18 are in Phase I; the rest remain preclinical.
LESSONS LEARNED: As for most "public health " technologies, notably vaccines and. contraceptives, the development of topical vaginal microbicides confronts the reluctance of the large pharmaceutical industry to invest in preventive technologies, especially those seen as having a primarily developing-world market and low profitability, and most especially those seen as harboring some kind of ideological or political risk. There have also been constraints deriving from public-sector apathy, insufficient human and financial resources, lack of coordination and focus, as well as skepticism about scientific feasibility. One of the major byproducts of these deficits is that, scientifically, the field has not attracted a critical mass of high-quality intellectual capital.

PRESENTER CONTACT INFORMATION

Name: Polly Harrison
Address: 6930 Carroll Ave, Suite 830
Takoma Park, MD 20912
Telephone: (301) 270-5924
Fax: (301) 270-5926